



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1459
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,958	12/26/2001	Dan L. Eaton	P3030RIC7	4529
EXAMINER				
KOLKER, DANIEL E				
ART UNIT		PAPER NUMBER		

7590 07/17/2006
Marc T Morley
Knobbe Martens Olson & Bear
2040 Main Street
14th Floor
Irvine, CA 92614

1649

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,958

Applicant(s)

EATON ET AL.

Examiner

Daniel Kolker

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22, 26-29 and 32-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-29, 32 and 38-44 is/are allowed.
- 6) ☒ Claim(s) 22 and 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/1/06.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 22, 26 – 29 and 32 – 44 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1 May 2006 has been entered.

Information Disclosure Statement

4. The IDS filed 1 May 2006 has been considered.

Withdrawn Rejections and Objections

5. The following rejections set forth in the previous office action are withdrawn:
 - A) The rejections of claims 22, 26, 33, and 35 – 41 under 35 USC 102(e) as being anticipated by, or in the alternative under 35 USC 103(a) as obvious over, Tang et al. are withdrawn. Applicant argues, on p. 6 of the remarks, that Exhibit A filed 1 May 2006 shows that the sequence from Tang is only 65.9% identical to SEQ ID NO:61. The examiner disagrees with applicant's assertion that the sequences are only 65.9% identical. The enclosed alignment of SEQ ID NO:61 from the instant application, reverse-translated by computer into nucleic acid and aligned with SEQ ID NO:1525 from Tang (09/491404) shows that the sequences are 92.2% identical. However, as the claims require at least 98% identity (see claim 22 for example), the prior art reference by Tang does not anticipate the invention now claimed.
 - B) The rejection of claims 22, 26 and 33 – 42 under 35 USC 103(a) as obvious over Tang and Lo is withdrawn. As set forth above, the nucleic acids taught by Tang are not within the scope of the invention now claimed.

Maintained Objections and Rejections

Priority

6. The effective priority date of the instant application is considered to be the filing date of the international application PCT/US00/05601, filed 1 March 2000 for the reasons made of record in the previous office action. Applicant did not traverse this statement.

Claim Rejections - 35 USC § 102

7. Claims 22 and 33 – 37 are rejected under 35 U.S.C. 102(e) as anticipated by Lal et al. (US Patent 6,063,767, issued 16 May 2000, filed 9 December 1998, claiming benefit of an application filed 28 October 1997, cited by applicant on IDS filed 1 May 2006), as evidenced by Alberts et al. (1994. Molecular Biology of the Cell, p. 582).

Lal et al. teach SEQ ID NO:3, which is 98.1% identical to applicant's SEQ ID NO:61 (see enclosed alignment). Thus Lal's SEQ ID NO:3 meets the structural limitations of claim 22, part(a) and claim 35. Lal is silent as to whether or not the polypeptide has the ability to induce mesangial cell proliferation or to induce fetal hemoglobin; these properties are explicitly recited in claim 22. However this is an inherent property of the protein product. Absent evidence to the contrary, the prior art protein is assumed to have this property, as the prior art meets all the structural limitations of the claimed product. The USPTO does not have the resources to test whether or not the prior art product has the ability to induce mesangial cell proliferation, and thus the burden is on applicant to provide evidence that the property is not provided for.

Claim 33 is drawn to heterologous fusion proteins comprising the polypeptide of claim 22. Lal specifically teaches said fusions with respect to any of the disclosed "PLBP" proteins (column 14 lines 49 – 59); note that SEQ ID NO:3 is also called "PLBP2" (column 5 lines 8 – 12). Thus Lal anticipates the invention of claim 33. The reference also teaches that the fusion protein can include a protein that can be recognized by commercially available antibodies, which is reasonably "a tag" as recited in claim 34. Claim 36 is drawn to a protein at least 98% identical to SEQ ID NO:61, lacking its signal peptide. Claim 36 can be interpreted to include proteins that are 98% identical to SEQ ID NO:61 over their full length, which then have the signal sequence cleaved off. Lal teaches that the signal peptide of SEQ ID NO:3 is from residues 1 – 21 of SEQ ID NO:3 (column 11 lines 65 – 66), and teaches methods of making the protein recombinantly by heterologous expression (see for example column 15 line 15 – column 16 line 25). Alberts et al. (see p. 582) provide evidence that such signal sequences are cleaved upon processing of

Art Unit: 1649

the protein, therefore Lal in fact teaches a protein at least 98% identical to SEQ ID NO:61, lacking its associated signal peptide. Claim 37 is drawn to proteins at least 98% identical to the protein encoded by the biological organism deposited with ATCC. While the reference by Lal does not mention said deposited organism, the instant specification discloses (paragraph spanning pp. 37 – 38) that the sequence in fact encodes SEQ ID NO:61, so Lal anticipates the invention of claim 37.

Conclusion

8. Claims 26 – 29, 32, and 38 – 44 are allowed.
9. Claims 22 and 33 – 37 are rejected.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Daniel E. Kolker, Ph.D.

July 10, 2006

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER